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(54) Title: A METHOD OF SELECTING AN INTRAOCULAR LENS TO BE IMPLANTED INTO AN EYE

(57) Abstract

A method of preoperatively selecting an intraocular lens to be implanted into an eye to postoperatively render the eye emmetropic or ametropic with any desired postoperative refraction, comprises the steps of a) determining the location of the lens haptic plane of the eye, b) determining the corneal power of the eye, c) determining the axial length of the eye, d) choosing the desired postoperative refraction, e) assuming a lens to be implanted, said lens having a known power and geometry, including the offset between the haptic plane of said lens and the anterior vertex of said lens as if it was in its implanted state, f) calculating from the parameters given by a), b), c), d) and e), as well as the refractive indices of ocular fluids, whether or not, postoperatively, focus will fall on the retina of the eye, g) if that is not the case, repeating steps d) - f) assuming another lens with a different power and/or geometry, until focusing on the retina is calculated in step f), and h) selecting for implantation, the lens of the nearest power available for which focusing on the retina is calculated in step f).

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A METHOD OF SELECTING AN INTRAOCULAR LENS TO BE IMPLANTED INTO AN EYE

TECHNICAL FIELD

The invention relates to a method of preoperatively selecting an intraocular lens to be implanted into an eye to postoperatively render the eye emmetropic or ametropic with any desired postoperative refraction.

BACKGROUND OF THE INVENTION

To obtain a desired postoperative refractive outcome of an intraocular lens implantation - emmetropia or ametropia -, there are several methods in use to determine which dioptric power the intraocular lens to be implanted, should have. The correct implant power to choose depends on the axial distance from the cornea, at which the intraocular lens (IOL) will end up in the eye.

With the present techniques, the axial position of the IOL can only be estimated.

Two major schools exist today for estimating the axial position of the IOL.

One school describes the optics of the eye in terms of thin lens theory.

In this connection reference is hereby made to:

1) Fedorov SN, Kolinko AL. Estimation of optical power of the intraocular lens. Vestn. Oftamol 1967;80(4):27-31,
2) Colenbrander MC. Calculation of the power of an iris clip lens for distant vision. Br J Ophthalmol 1973;57:735-740,
3) Hoffer KJ. Mathematics and computers in intraocular lens calculation. Am Intra-Ocular Implant Soc J 1975;1(1):4-5,
4) van der Heijde GL. A nomogram for calculating the power of the prepupillary lens in the aphakic eye. Bibliotheca Ophthalmol 1975;83:273-275,

5) Thijssen JM. The emmetropic and the iseikonic implant lens: computer calculation of the refractive power and its accuracy. Ophthalmologica 1975;171:467-486,

6) Binkhorst RD. The optical design of intraocular lens implants. Ophthalmic Surg 1975;6(3):17-31, and

7) Holladay JT, Prager TC, Chandler TY, et al. A three-part system for refining intraocular lens power calculations. J Cataract Refract Surg 1988;14:17-24.

The axial position of the IOL is mostly considered to be a constant, often referred to as the ACD constant. The value of the constant depends to some extent on the IOL model. In the thin lens theory, this constant represents the postoperative distance between the principal planes of the cornea and of the IOL.

Another school applies retrospective statistical analysis of clinical data to determine a coefficient, the so called A-constant, in a linear equation, known as the SRK formula, linking corneal dioptric power K, eye length L, IOL power and postoperative refraction.

In this connection reference is made to:

8) Sanders DR, Retzlaff J, Kraff M, et al.: Comparison of the accuracy of the Binkhorst, Colenbrander, and SRK™ implant power prediction formulas. Am Intra-Ocular Implant Soc J 1981; 7:337-340,

9) Sanders DR, Retzlaff J, Kraff MC. Comparison of the SRKII™ formula and other second generation formulas. J. Cataract Refract Surg 1988;14:136-141, and

10) Sanders DR, Retzlaff J, Kraff MC, Gimbel HV, Raanan MG. Comparison of the SRK/T formula and other theoretical and regression formulas. J Cataract Refract Surg 1990; 16:341-346.

The linear relationship mentioned above, is not a theoretically correct representation of the optics of the eye, but the SRK approach is most widely used because it is simple and, in clinical practice, yields results similar to the thin

lens theory approach.

The SRK/T formula in the above reference 10), is a hybrid between the two approaches.

In both schools, further refinement entails corrections depending on mainly eye length.

The following references:

11) Olsen T. Theoretical approach to intraocular lens calculation using Gaussian optics. J Cataract Refract Surg 1987; 13:141-145,

12) Haigis W. Strahldurchrechnung in Gausscher Optic zur Beschreibung des Linsen-Systems Brille-Kontaktlinse-Hornhaut-Augenlinse (IOL), in: Schott K, Jacobi KW, Freyler H (Hrsg): 4 Kongr. d. Deutsch. Ges. f. Intraokularlinsen Implant., Essen 1990. Berlin, Heidelberg, New York, Springer Verlag 1990, and

13) Kashiwagi T. Ray tracing error correction in ophthalmic optics. J Cataract Refract Surg 1991; 17:194-198,

apply thick lens theory, which is physically more exact, but the general problem of pre-estimating the axial position of the IOL remains.

The position of the IOL optic is determined by its fixation in the eye. Fixation is mostly obtained by means of attachments to the optic, so called loops, that hold the lens in place by spring action against ocular tissue. The most common site of placement of the IOL today is inside the capsular bag. Alternative placements are in the ciliary sulcus and in the anterior chamber angle. Lenses that are fixed to the iris also exist, but fixation is then not by spring action. There are also lenses meant for capsular bag placement that do not possess loops or exert spring action, such as disc lenses, plate lenses, and capsular bag filling lenses.

The object of the invention is to bring about a method of preoperatively selecting an intraocular lens to be implanted into an eye to postoperatively render the eye emmetropic or

with any other chosen refractive outcome, which method should be applicable to all types of IOLs.

This is attained by the method according to the invention, which comprises the steps of

a) determining the location of the lens haptic plane of the eye,

b) determining the corneal power of the eye,

c) determining the axial length of the eye,

d) choosing the desired postoperative refraction,

e) assuming a lens to be implanted, said lens having a known power and geometry, including the offset between the haptic plane of said lens and the anterior vertex of said lens as if it was in its implanted state,

f) calculating from the parameters given by a), b), c), d) and e), as well as the refractive indices of ocular fluids, whether or not, postoperatively, focus will fall on the retina of the eye,

g) if that is not the case, repeating steps d) - f) assuming another lens with a different power and/or geometry, until focusing on the retina is calculated in step f), and

h) selecting for implantation, the lens of the nearest power available for which focusing on the retina is calculated in step f).

PREFERRED EMBODIMENTS

For all IOLs, a plane, the lens haptic plane (LHP), can be determined according to the invention. This plane is perpendicular to the optical axis of the eye and defines the plane of fixation of the IOL in the eye.

Given the location of this plane, i.e. actually its distance from the anterior cornea, the position of the optic in relation to it, is determined by the design of the lens.

For placement of the IOL in a particular site, e.g. the capsular bag, this plane should be independent of the lens model. Given the corneal dioptric power K, or, which is

equivalent, corneal thickness and radii, the eye length L, the location of the LHP from the anterior cornea, and the lens design, an exact calculation of the IOL dioptric power to render the eye emmetropic, or with any other desired refractive outcome, can be made according to the invention.

According to the invention, the following steps are carried out:

The location of the LHP of the eye in which the IOL is to be implanted is determined, as are, by methods known per se, the corneal power and the axial length of that eye. Moreover, the desired refractive outcome, usually emmetropia, is chosen.

Then, a lens having a known dioptric power and geometry as provided by the manufacturer, is assumed to be implanted.

Any offset between said determined LHP and the anterior vertex of the lens assumed to be implanted, is determined from the geometry of the lens, whereupon from the determined corneal power, the determined axial length, and the determined offset as well as the power and geometry of the assumed lens, and the refractive indices of cornea and ocular fluids, it is calculated whether or not, postoperatively, the eye will obtain the desired refractive outcome with the assumed lens.

If that is not the case, another lens with a different power and/or geometry, is assumed, and the above calculations are repeated until focus on the retina is calculated. The lens of the nearest available power for which this is calculated, is then selected for implantation.

According to the invention, there are both indirect and direct methods available to preoperatively determine the location of the LHP, i.e. the distance from the anterior cornea to the LHP.

The distance from the anterior cornea to the anterior cata-

ract can be measured by A-scan biometry. As mentioned above, this distance is termed ACD (ultrasonic or geometrical ACD). The thickness, LEN, of the cataract can also be determined by A-scan biometry. The distance from the anterior cornea to the LHP must be greater than ACD, since the IOL is placed within the subsequently empty capsular bag. The following formula is postulated:

$$LHP = ACD + \alpha x LEN,$$

where α is a constant, which as suggested by preliminary analysis of clinical data, is between 0 and 0.25, preferably between 0.15 and 0.2. This method is somewhat indirect, but can be applied by means already in routine use.

Based on the same parameters, the following formula can also be used:

$$LHP = \beta x(ACD + LEN),$$

where β is a constant, which as suggested by preliminary analysis of clinical data, is between 0.3 and 0.7, preferably around 0.5.

With reference to:

14) Pavlin CJ, Sherar MD, Foster FS. Subsurface ultrasonic microscopic imaging of the intact eye, Ophthalmology 1990; 97:244-250,

15) Pavlin CJ, Harasiewicz K, Sherar MD, Foster FS. Clinical use of ultrasound biomicroscopy. Ophthalmology 1991; 98: 287-295,

16) Pavlin CJ, Rootman D, Arshinoff S, et al. Determination of haptic position of transsclerally fixated posterior chamber intraocular lenses by ultrasound biomicroscopy. J. Cataract Refract Surg 1993; 19:573-577, and

17) Pavlin CJ, Harasiewicz K, Foster FS. Ultrasound biomicroscopic analysis of haptic position in late-onset, recurrent hyphema after posterior chamber lens implantation. J Cataract Refract Surg 1994; 20:182-185,

the anterior structure of the eye can be mapped in three dimensions by means of ultrasound biomicroscopy. The axial

position of the anterior chamber angle, the iris and the ciliary sulcus can be unequivocally determined, and hence the location of the LHP for these placements. The position of the LHP for capsular bag placement can be related to the axial position of the anatomy proximal to the capsular bag equator, e.g. the equator itself, the zonula and/or the ciliary body.

With reference to:
18) Bell J. Interferometry reveals eye's microstructure. Opto & Laser Europe, Issue 12, August 1994,
the location of the LHP can be directly determined by means of both optical coherence tomography and optical coherence microscopy.

The location of the LHP can also be determined by means of Scheimpflug photography in that Scheimpflug cameras are generally available nowadays.

Following schemes in a general text book on optics, namely:
19) O'Shea DC. Elements of modern optical design. New York, Wiley-Interscience, 1985,
ray-tracing calculations for the paraxial ray, a meridional ray or any other ray, can be made. The paraxial ray-trace is tantamount to the application of thick lens theory, also known as Gaussian optics. The meridional ray-trace employs exact geometrical optics. The meridional and the paraxial ray-traces are equivalent for rays close to the optical axis.

A more sophisticated method to obtain best focus is by so called modulation transfer function (MTF) calculations. The performance of an optical system is best described by its optical transfer function (OTF). OTF has a real part, MTF, and an imaginary part, PTF (phase transfer function). Usually, one is only concerned about the MTF for which a theoretical upper limit, the diffraction limit, exists.

It is important that an optical system transfers spatial frequencies with a minimum of distortion.

The modulation, commonly called the MTF, is normalized to be 1 at zero spatial frequency (very large objects). The limiting MTF curve monotonically approaches 0 at the Rayleigh limit, the highest spatial frequency (finest detail) that can be transmitted by the optical system. The MTF curves of real systems obviously fall below the limiting curve.

The best focus, defined as the position at which MTF is maximal, of a system depends to some extent on the spatial frequency being focused at. A spatial frequency of 100 cycles per millimetre corresponds approximately to a level of fineness associated with visual acuity 20/20 (American terminology); 1.0 (European terminology); which is the line on the Snellen chart eye doctors and opticians consider as "full" vision.

For an optical system, one can calculate the maximum MTF for any given spatial frequency, wherein 100 cycles per millimetre would be a logical choice. The calculation is either "geometrical" or "diffractive". The latter is more precise and takes the wave nature of light into account. The calculation can also take the Stiles-Crawford effect into account. The retinal receptors are more sensitive for light perpendicular to the retinal surface. This directional preference is the Stiles-Crawford effect.

The "best" focus obtained by MTF calculations - or meridional ray-tracing - typically lies in front of the paraxial focus. At present, the measurement precision for IOL power calculation does not warrant more sophistication than the paraxial ray-trace (Gaussian optics).

The great advantage of the method according to the invention in comparison to methods known so far, is that it enables the calculation of IOL implant power on preoperatively measurable parameters, that it relates the IOL placement to the anatomy of the eye and that it is independent of intraocular lens models, provided that IOL manufacturers divulge the necessary design information.

The basic idea of the invention is to calculate where along the eye's optical axis the implanted IOL must be positioned in order to satisfy the optical condition to focus on the retina, given the pre-clinical eye measurements and the desired postoperative refraction.

To postoperatively measure ACD serves as an independent corroboration of the correctness of the calculation. If there are no measurement errors, the calculated ACD (anterior cornea to anterior IOL) and the measured ACD (geometrical) should coincide.

With a manufacturer's knowledge of the exact design of an IOL model, there is a simple geometric relationship between the position of the LHP and ACD. The offset between the LHP and the anterior vertex of the IOL depends on the design of the lens and its dioptric power, hence the relationship between LHP and ACD.

For any new IOL model, the dioptric power to render the eye emmetropic or with any desired refractive performance can be calculated, without recourse to ACD constants, A-constants, or any other type of constants, which is the practice today.

WHAT IS CLAIMED IS:

1. A method of preoperatively selecting an intraocular lens to be implanted into an eye to postoperatively render the eye emmetropic or ametropic with any desired postoperative refraction, comprising the steps of
a) determining the location of the lens haptic plane of the eye,
b) determining the corneal power of the eye,
c) determining the axial length of the eye,
d) choosing the desired postoperative refraction,
e) assuming a lens to be implanted, said lens having a known power and geometry, including the offset between the haptic plane of said lens and the anterior vertex of said lens as if it was in its implanted state,
f) calculating from the parameters given by a), b), c), d) and e), as well as the refractive indices of ocular fluids, whether or not, postoperatively, focus will fall on the retina of the eye,
g) if that is not the case, repeating steps d) - f) assuming another lens with a different power and/or geometry, until focusing on the retina is calculated in step f), and
h) selecting for implantation, the lens of the nearest power available for which focusing on the retina is calculated in step f).

2. The method as claimed in claim 1, comprising determining the location of the lens haptic plane by measuring the distance from the anterior cornea to the anterior cataract in the eye, measuring the thickness of the cataract, and adding said measured thickness, multiplied by a clinically determined constant, to said measured distance.

3. The method as claimed in claim 2, wherein said constant is between 0 and 0.25.

4. The method as claimed in claim 3, wherein said constant is between 0.15 and 0.2.

5. The method as claimed in claim 1, comprising determining the location of the lens haptic plane by measuring the distance from the anterior cornea to the anterior cataract in the eye, measuring the thickness of the cataract, and multiplying said measured distance added to said measured thickness by a clinically determined constant.

6. The method as claimed in claim 5, wherein said constant is between 0.3 and 0.7.

7. The method as claimed in claim 6, wherein said constant is around 0.5.

8. The method as claimed in claim 2 or 5, comprising measuring said distance and said thickness by ultrasound biometry.

9. The method as claimed in claim 1, comprising determining the location of the lens haptic plane by means of ultrasound biomicroscopy.

10. The method as claimed in claim 1, comprising determining the location of the lens haptic plane by means of optical coherence tomography.

11. The method as claimed in claim 1, comprising determining the location of the lens haptic plane by means of optical coherence microscopy.

12. The method as claimed in claim 1, comprising determining the location of the lens haptic plane by means of Scheimpflug photography.

13. The method as claimed in claim 1, comprising carrying out the calculation in step f) by optical ray-tracing, by thin lens calculations or by thick lens calculations.

14. The method as claimed in claim 1, comprising carrying out the calculation in step f) by computation of the maximum obtainable modulation of the optical transfer function for

any spatial frequency.

15. The method as claimed in claim 14, comprising choosing the spatial frequency to be 100 cycles per millimetre.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE 96/00577

A. CLASSIFICATION OF SUBJECT MATTER

IPC6: A61F 2/16
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC6: A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

WPI, CLAIMS

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5282852 A (T.G. CAPETAN ET AL), 1 February 1994 (01.02.94), see whole document ---	1-15
A	US 4710193 A (D. VOLK), 1 December 1987 (01.12.87), column 4, line 16 - column 12, line 59 --- --------	1-15

☐ Further documents are listed in the continuation of Box C. ☒ See patent family annex.

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INTERNATIONAL SEARCH REPORT

Information on patent family members

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Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US-A- 5282852	01/02/94	NONE	
US-A- 4710193	01/12/87	AU-A- 1046188	14/06/89
		DE-D,T- 3787732	10/03/94
		EP-A,B- 0419451	03/04/91
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